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Is Viagra® Worth a Try?

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As reported in MBM's November 7, 2008 Newsflash, the "obvious to try" test was recently adopted by the Supreme Court of Canada in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*¹ ("*Sanofi*"). Now, the first decision by the Federal Court of Appeal interpreting *Sanofi* has been rendered on January 16, 2009 in *Apotex Inc. v. Pfizer Canada Inc.*², and suggests that the refined test for obviousness may not necessarily lead to more successful challenges of patent claims on that basis.

The decision was rendered in proceedings involving the *Patented Medicines (Notice of Compliance) Regulations* for the well-known drug Viagra (sildenafil). The trial judge had allowed the application brought by Pfizer to prohibit the Minister of Health from issuing a Notice of Compliance ("NOC") to Apotex for its sildenafil-containing drug until expiry of Canadian Patent No. 2,163,446 (the '446 patent) directed to the use of sildenafil (and other compounds) for the treatment of erectile dysfunction. Corresponding patents in other jurisdictions have been found invalid on various bases, but Apotex relied, in part, on the U.K. decision that included obviousness as a ground of invalidation.

The main point argued by Apotex on appeal was whether or not *Sanofi* incorporated into the Canadian law on obviousness the "worth to try" test as elaborated by U.K. decisions such as the *Lilly Icos Ltd. v. Pfizer Ltd.*, [2002] EWCA Civ 1 which invalidated the same patent in the U.K. on the ground of obviousness. According to Apotex, the "worth to try" test is now part of Canadian law and, as such, the trial judge failed to apply to proper test in analyzing the '446 patent in light of the old test established in *Beloit Canada Ltd. et al. v. Valmet Oy*³.

The Federal Court of Appeal (the "Court") rejected Apotex's position and confirmed a distinctly Canadian approach to the "obvious to try" question. According to the Court, the test adopted by the Supreme Court of Canada in *Sanofi* is "obvious to try" not "worth to try", where the word "obvious" means "very plain". The mere possibility or speculation that something might work is not sufficient - the invention must be more or less self-evident.

In the case at hand, however, a review of the trial judge's assessment of the evidence revealed that his analysis was in line with the *Sanofi* "obvious to try" test. Although the

¹ 2008 SCC 61.

² 2009 FCA 8.

³ (1986) 8 C.P.R. (3d) 289, 64 N.R. 287 (F.C.A.).

four-part test was not applied specifically, the trial judge had turned his mind to the question of whether or not the invention was more or less self-evident and had, according to the Court, drew the line precisely where the Supreme Court drew it in *Sanofi*, i.e. that “the mere possibility that something might turn up is not enough”. Accordingly, it was found that the trial judge had applied the correct test and the appeal was dismissed.

The Court also commented on the U.K. *Lilly Icos* decision mentioned above which, in his view, was determined on the basis of a test for obviousness that is broader than that adopted in *Sanofi*. According to the Court, the reasoning approved by the English Court of Appeal in that decision to the effect that where the motivation to achieve a result is very high, the degree of expected success becomes a minor matter, was expressly rejected by the Supreme Court in *Sanofi*. Instead, motivation should, according to the Court, be relevant in determining whether the skilled person has good reason to pursue “predictable” solutions or solutions that provide “a fair expectation of success”, an approach more in line with the well-known U.S. *KSR International Co. v. Teleflex Inc.* and the more recent U.K. *Angiotech Pharmaceuticals Inc. v. Conor Medsystems Inc.* decisions. Thus, in the words of the Court, a solution may be “worthwhile” to pursue even though it is not “obvious to try” or not “more or less self-evident”.

This decision stands in contrast to the U.K. decision and suggests that the Canadian approach to obviousness may be more rigid. It is important to keep in mind, however, that *Patented Medicines (Notice of Compliance) Regulations* proceedings are summary in nature and do not affect or confirm the validity of a patent *per se*. The finding that is made under such a prohibition proceeding is whether or not a second manufacturer’s allegation of invalidity (or non-infringement) is justified and to determine whether said manufacturer can be issued an NOC. Thus, it remains open to Apotex to challenge the validity of the ‘446 patent in a patent impeachment suit under the *Patent Act*. In fact, it appears that such a suit was recently filed by Apotex on May 13, 2009. The judge presiding over said suit will, in principle, be required to establish the facts of the case *de novo*, hear additional evidence, as the case may be, and apply the relevant legal tests with a judicial anxiety to uphold a useful patent - a well established principle under Canadian patent law⁴.

⁴ *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504, 56 C.P.R. (2d) 146.